510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

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AUG 16 2013

This summary was prepared on June 14, 2013.

2. Names and classification of the devices

Trade name: IntelliVue Patient Monitors MP5 and MP5SC, Revision J.21.
Common name: Multiparameter Patient Monitor

Classification names are as follows:

Device Panel	Classification	ProCode	Device Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart

Device Panel	Classification	ProCode	Device Description
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	§868.2775, II	KOI	Electrical peripheral nerve Stimulator
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological Devices	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The subject devices Philips IntelliVue Patient Monitors MP5 and MP5SC, both with software revision J.21 are substantially equivalent to previously cleared Philips IntelliVue Patient Monitors MP5 and MP5SC marketed pursuant to K122439, K120366, K113657, K113441, K110474, K110622, K102562, K101449, K100939,

K093268, K091927, K091395, K083517, K083228, K082633, K082583, K081793, K072070, K071426, K063725, K063315, K062392

4. Description of the Devices

The Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models: IntelliVue Patient Monitors MP5 and MP5SC, that consist of display units including built-in and central processing units (CPU) and physiological measurements. All monitors share the same system architecture and exactly the same software is executed on each monitor.

The IntelliVue Patient Monitors measure multiple physiological parameters such as surface ECG, invasive and non-invasive pressure, etc., generate alarms, record physiological signals, store derived data, and communicate derived data and alarms to central stations via the IntelliVue Clinical Network.

The subject modification introduces the optional Philips Tympanic Temperature Module (866149) for the IntelliVue Patient Monitors MP5 and MP5SC. This Tympanic Temperature Module extends the capability of the IntelliVue Patient Monitors MP5 and MP5SC to interface the Genius™ 2 Tympanic Temperature Probe (cleared by Covidien, K060649).

Additionally the software revision J.21 is made available for the IntelliVue Patient Monitors MP5 and MP5SC.

5. Intended Use

The subject devices IntelliVue Patient Monitors MP5 and MP5SC have the same Intended Use as the legally marketed predicate IntelliVue Patient Monitors MP5 and MP5SC.

The Indications for Use of the subject Philips IntelliVue Patient Monitors MP5 and MP5SC have not changed as a result of the device modification.

The subject and predicate devices IntelliVue Patient Monitors MP5 and MP5SC have the following detailed Indications for Use Statements in their Instructions for Use:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.

The monitors are intended for use by trained healthcare professionals in a hospital environment.

The MP5 and MP5SC monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5 and MP5SC when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

6. Technological Characteristics
The subject devices IntelliVue Patient Monitors MP5 and MP5SC have the same technological characteristics such as design, energy sources, portability, user interface, performance, and robustness as the legally marketed predicate IntelliVue Patient Monitors MP5 and MP5SC devices. The physical specifications of all devices and performed V&V testing have demonstrated the equivalence of the devices with respect to the intended use. Biocompatibility aspects of the Philips IntelliVue Patient Monitors MP5 and MP5SC are not affected and have not changed, the Covidien Genius™ 2 Tympanic Temperature Probe was cleared by Covidien under K060649.

7. Summary of Verification & Validation Activities

Testing according to the recognized consensus standards:

- IEC 60601-1-2:2001 +A1:2004 (EMC)
- IEC 60601-1:1988 +A1:1991+A2:1995 (General Safety)

All applicable requirements have been met.

Environmental testing (temperature, humidity), mechanical testing (shock, vibration, and free fall).
All specified test requirements have been met. The tests confirmed that the IntelliVue Patient Monitors MP5 and MP5SC worked safely and according to their specifications and indicated claims during tests simulating general hospital conditions, handling and transport in hospital environments, and storage.

Software Functionality and as required by the Hazard Analysis testing on the IntelliVue Patient Monitors MP5 and MP5SC.

All specified criteria have been met. The tests demonstrated that the IntelliVue Patient Monitors MP5 and MP5SC worked safely, effectively, and correctly in accordance with specifications and labeling claims in the intended environment of use.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate.
Testing involved system level and as well as testing from the hazard analysis.
Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.
The results demonstrate that the Philips IntelliVue Patient Monitors MP5 and MP5SC meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Philips Medizinsysteme Boeblingen Gmbh
c/o Mr. Herbert Van Dyk
Quality and Regulation Function Manager
Hewlett-packard Str. 2
Boeblingen, GM D 71034

Re: K131829
Trade/Device Name: Intellivue Patient Monitor (MP5 and MP5SC)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DRT, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DPS, MLC, DRW, KRC, DRJ, DQA, DSP, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: July 15, 2013
Received: July 17, 2013

Dear Mr. Herbert Van Dyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 Indications Statement

Indications for Use MP5 and MP5SC

510(k) Number (if known):_____

Device Name: Philips IntelliVue patient monitors MP5 and MP5SC, software revision J.21.

MP5 and MP5SC IntelliVue Patient Monitors:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The MP5 and MP5SC monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5 and MP5SC when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.
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The Predictive Temperature measurement is intended for use with adult and pediatric patients in a hospital environment.
The SSC Sepsis Protocol, in the Protocol Watch clinical decision support tool, is intended for use with adult patients only.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

Prescription Use (Part 21 CFR 801 Subpart D) - ___Yes___ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) ___No___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)